REMARKS

This Response is submitted in reply to the non-final Office Action mailed on September 8, 2006. No fee is due in connection with this Response. The Director is authorized to charge any fees which may be required, or to credit any overpayment to Deposit Account No. 02-1818. If such a withdrawal is made, please indicate the Attorney Docket No. 112703-35 on the account statement.

Claims 1-12, 19-22 and 26-29 are pending in this application. Claims 13-18 and 23-25 were previously canceled. In the Office Action, Claims 1-12, 19-22 and 26-29 are rejected under 35 U.S.C. §112, second paragraph, and Claims 1-12, 19-22 and 26-29 are rejected under 35 U.S.C. §103. For the reasons set forth below, Applicants respectfully submit that the rejection should be withdrawn.

In the Office Action, Claims 1-12, 19-22 and 26-29 are rejected under 35 U.S.C. §112, second paragraph, as allegedly being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicants regard as the invention. The standard for determining whether the definitiveness requirement is met under 35 U.S.C. § 112, second paragraph, is "whether those skilled in the art would understand what is claimed when the claim is read in light of the Specification." *Orthokinetics Inc. v. Safety Travel Chairs Inc,* 1 U.S.P.Q. 2d 1081-1088 (Fed. Cir. 1986). Applicants respectfully disagree with the Patent Office's rejection under 35 U.S.C. § 112, second paragraph, and submit that the scope of the present claims are clear to one having ordinary skill in the art in view of the specification and experiment examples.

The present claims are rejected because the Patent Office alleges that the phrase "less than the typical amount" is unclear as to what amount is necessary for use in the claimed chewing gum. In response, Applicants previously submitted an Affidavit under 37 C.F.R. §1.132 (a courtesy copy of the "*Affidavit*" is attached hereto as Exhibit A), which evidences that one having ordinary skill in the art would understand the metes and bounds of Claims 1, 7 and 19.

As supported by the *Affidavit*, one having ordinary skill in the art one would understand that in view of the specification the phrase "less than the typical amount of medicament than is swallowed by the individual to achieve a bioequivalent effect" refers to a smaller effective amount of medicament provided in the claimed chewing gum that can achieve the same

bioequivalent effect as a larger typical or standard amount of that same medicament taken orally (e.g. swallowed in a tablet or capsule). The typical or standard amounts of a medicament or active agent given in capsule or table forms are usually pre-determined standard amounts in a given industry (e.g. pharmaceutical, food) known by the skilled artisan for achieving a particular objective (e.g. alleviate a headache, increase alertness).

The specification teaches that the claimed invention is intended to apply to a wide range of drugs and agents (page 8, lines 22-33), and one of ordinary skill in the art would understand that absolute amounts of the active agents in gum can depend upon the agent given and the result to be achieved. While exemplary amounts have been provided in the specification in certain instances, for example at page 9 at lines 1-25; as indicated at page 9, lines 26-31, exact dosing regimens will depend on the agent or medicament, the person taking the medicament and the desired result.

Appellants respectfully disagree with the Patent Office's assertion that one having ordinary skill in the art would not be able to determine what the various typical dosage amounts would be for all types of medicaments based on this standard in view of the multitude of drug classes claimed. See, Office Action, page 2. As discussed previously, the lower bioequivalent amount of medicament in a chewing gum would always be correlated to a specified amount of medicament that is typically swallowed for a certain effect.

For example, assume an individual wants to take two aspirin tablets containing a total of 500 mg to treat his mild headache. Instead, the claimed method involves giving the individual a chewing gum having an aspirin amount less than 500 mg (e.g. 300 mg) and still achieve the bioequivalent effect as if the individual has swallowed two aspirin tablets totaling 500 mg aspirin because of the adsorption through the oral mucosa. Assume an individual wants to take two aspirin tablets containing a total of 750 mg to treat his headache because it is more severe. Instead, the claimed method involves giving the individual a chewing gum having an amount less than 750 mg (e.g. 500 mg) and still achieve the bioequivalent effect of 750 mg of aspirin tablets.

Just as the typical dosage forms of the medicament tablet or capsule may vary depending on the individual's desire or need, so to can the medicament amount in the chewing gum. Indeed, the chewing gums can be provided to individuals based on the corresponding amount of

medicament in tablet or capsule form they desire and still contain the bioequivalent yet lower dosage. Moreover, the smaller amounts needed in the chewing gum to achieve the bioequivalent of the desired or typical dosage forms can be readily determined through routine experimentation.

One having ordinary skill in the art would understand and be able to readily determine what "typical amounts" of a medicament or drug given in a tablet or capsule form are, for example, using guidelines known in the particular industry. For FDA approved drugs, typical or standard amounts would be the approved amounts. In fact, the typical or standard amounts are generally pre-defined and uniform in the pharmaceutical or food industry. Otherwise, how could any product be dispensed to the public at large or a physician or other healthcare provider dispense any pharmaceutical compound. The literature is replete with documentation on what is typically or commonly administered to treat a disorder. Consequently, those skilled in the art readily know or can determine what this amount is.

The amount of medicament used in the claimed gum formulation would clearly be the amount that delivers the bioequivalent of an approved dosage and will be less than the standard amount given in a capsule or tablet because of the improved absorption efficiency through the oral mucosa. Where different dosages are approved and used, various gum compositions would deliver bioequivalent amounts for the different approved dosages. For other agents, typical or standard amounts can easily be identified by one having skill by reading the ingredient listing on a package insert or by testing using various analytical techniques such as chromatography. The specific amount of an medicament agent incorporated into a gum for delivering a bioequivalent amount will be less than the pre-determined amount given in a tablet or capsule and can be ascertained by one skilled in the art using available methods.

Furthermore, Applicants respectfully submit that the numerous examples and experiments set forth in the specification demonstrate the claimed chewing gum having less than the typical amount of a medicament to achieve a bioequivalent effect of a swallowed medicament. As discovered by the Applicants, the administration of the medicament or agent via a chewing gum through the buccal cavity can provide an increased effect than when the same medicament or agent is taken through enteral or oral administration (e.g. swallowed via capsules or tablets). For example, this is demonstrated with the caffeine study of Experiment 2 comparing

the bioequivalent effect/bioavailability of caffeine in consumers' bloodstream after chewing caffeine containing gum versus swallowing caffeine pills. These examples demonstrate that less caffeine can be provided in the claimed product than that that is typically ingested, for example, through No Doze, and still achieve as good if not greater bioequivalent effect. In fact, Applicants are able to achieve a equivalent bioavailability utilizing an oral drug delivery system that approaches that of a parenteral administration.

In sum, Applicants respectfully submit that those skilled in the art would understand the metes and bounds of the claims when read in light of the specification and experimental examples. Based on at least these noted reasons, Applicants believe that Claims 1, 7 and 19 and Claims 2-6, 8-12, 19-22 and 26-29 that depend from Claims 1, 7 and 19 fully comply with 35 U.S.C. §112, second paragraph.

Accordingly, Applicants respectfully submit that the rejection of Claims 1-12, 19-22 and 26-29 under 35 U.S.C. §112, second paragraph, is improper and the rejection be withdrawn.

In the Office Action, Claims 1-12, 19-22 and 26-29 are rejected under 35 U.S.C. §103 as being unpatentable over Aspergum® ("*Aspergum*") in view of WO 98/23165 to Gudas et al. ("*Gudas*"). Claims 1-12, 19-22 and 26-29 are rejected under 35 U.S.C. §103 as being unpatentable over Aspergum® ("*Aspergum*") in view of U.S. Patent No. 5,922,347 to Hausler et al. ("*Hausler*"). Applicants believe these rejections are improper and respectfully traverse them for at least the reasons set forth below.

Independent Claims 1, 7 and 19 recite, in part, providing a chewing gum including less than a typical amount of medicament than is swallowed by the individual to achieve a bioequivalent effect and chewing the chewing gum to cause the medicament to be released from the chewing gum composition into the buccal cavity of the individual. In contrast, Applicants respectfully submit that there is no suggestion or motivation to combine the cited references to obtain the present claims, and even if combinable, all of the claimed elements are not taught or suggested by the cited references.

Applicants respectfully submit that there is no suggestion or motivation to combine *Aspergum* and *Gudas* to obtain the present claims. *Aspergum* is entirely directed to a product comprising Aspirin for the treatment of minor aches and pains. On the other hand, *Gudas* is

entirely directed to chewing gum comprising caffeine. Thus, there is no direction provided in the cited references suggesting how they should be combined to obtain the present claims.

Moreover, *Gudas* teaches that the caffeine is encapsulated thereby likely leading to a delayed release of the caffeine in the oral cavity (*Gudas*, page 11, lines 14-25). For example, *Gudas* teaches that delaying the release of caffeine can reduce the bitter taste of caffeine (e.g. by avoiding release in the buccal cavity), which teaches away from the present claims. See, *Gudas*, page 1, line 36 to page 2, line 2. Consequently, neither *Aspergum* nor *Gudas* teaches or even addresses the objectives of Applicants' claimed invention, and thus, the skilled artisan would have no reasonable expectation of success in combining the cited references to arrive at the present claims.

Applicants also respectfully submit that, even if combinable, *Aspergum* and *Gudas* do not disclose or suggest all of the claimed elements. For example, *Aspergum* fails to disclose or suggest providing a chewing gum including less than a typical amount of medicament than is swallowed by the individual to achieve a bioequivalent effect as required, in part, by Claims 1, 7 and 19. The Patent Office admits same. See, Office Action, page 3, lines 19-20. *Gudas* also fails to disclose or suggest providing a chewing gum including less than a typical amount of medicament than is swallowed by the individual to achieve a bioequivalent effect as required, in part, by Claims 1, 7 and 19. *Aspergum* and *Gudas* also fail to disclose or suggest chewing the chewing gum to cause the medicament to be released from the chewing gum composition into the buccal cavity of the individual required, in part, by Claims 1, 7 and 19. *Aspergum* is silent with respect to these elements, and *Gudas* teaches encapsulating the caffeine to delay its release and thereby avoid the bitter taste of caffeine, which teaches away from the present claims.

Finally, Applicants respectfully submit that, even if combinable, *Aspergum* and *Hausler* do not disclose or suggest all of the claimed elements. For example, *Aspergum* fails to disclose or suggest providing a chewing gum including less than a typical amount of medicament than is swallowed by the individual to achieve a bioequivalent effect as required, in part, by Claims 1, 7 and 19. The Patent Office admits same. See, Office Action, page 3, lines 19-20. *Hausler* also fails to disclose or suggest providing a chewing gum including less than a typical amount of medicament than is swallowed by the individual to achieve a bioequivalent effect as required, in part, by Claims 1, 7 and 19. In fact, *Aspergum* and *Hausler* are completely silent with respect to

these elements, and the Patent Office has failed to provide any support in *Aspergum* and *Hausler* regarding same.

What the Patent Office has done is to rely on hindsight reconstruction of the claimed invention. Applicants respectfully submit that it is only with a hindsight reconstruction of Applicants' claimed invention that the Patent Office is able to even attempt to piece together the teachings of the prior art so that the claimed invention is allegedly rendered obvious. Instead, the claims must be viewed as a whole as defined by the claimed invention and not dissected into discrete elements to be analyzed in isolation. *W.L. Gore & Assoc., Inc. v. Garlock, Inc.*, 721 F.2d 1540, 1548, 220 USPQ 303, 309 (Fed. Cir. 1983); *In re Ochiai*, 71 F.3d 1565, 1572, 37 USPQ2d 1127, 1133 (Fed. Cir. 1995). One should not use hindsight reconstruction to pick and choose among isolated disclosures in the prior art to deprecate the claimed invention. *In re Fine*, 837 F.2d at 1075. (Fed. Cir. 1988).

For at least the reasons discussed above, the combinations of *Aspergum* and *Gudas* or *Aspergum* and *Hausler* are improper or do not teach, suggest, or even disclose all of the elements of the present claims, and thus, fail to render the claimed subject matter obvious.

Accordingly, Applicants respectfully request that the obviousness rejections with respect to Claims 1-12, 19-22 and 26-29 be reconsidered and the rejections be withdrawn.

Claims 3, 6 and 11 are rejected under 35 U.S.C. §103(a) as being unpatentable over *Aspergum*. Claim 26 is rejected under 35 U.S.C. §103(a) as being unpatentable over *Aspergum* in view of *Gudas*. Applicants respectfully submit that the patentability of Claims 1, 7 and 19 as previously discussed renders moot the obviousness rejections of 3, 6, 11 and 26 that depend from Claims 1, 7 and 19. In this regard, the cited art fails to teach or suggest the elements of 3, 6, 11 and 26 in combination with the novel elements of Claims 1, 7 and 19.

For the foregoing reasons, Applicants respectfully request reconsideration of the above-identified patent application and earnestly solicit an early allowance of same.

Respectfully submitted,

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BY _____

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Dated: December 6, 2006

EXHIBIT A

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant(s): Ream et al.
Appl. No.: 09/286,818
Conf. No.: 5472
Filed: April 6, 1999
Title: PHARMACEUTICAL CHEWING GUM FORMULATIONS
Art Unit: 1615
Examiner: Hawes, P.A.
Docket No.: 112703-035

AFFIDAVIT UNDER 37 C.F.R. § 1.132

Sir:

I, Ronald Ream, hereby state as follows:

1. My experience and qualifications are as follows:
   - B.S. in Chemistry from Northern Illinois University – 1964
   - M.B.A. from Loyola University in Chicago – 1970
   - Advanced Certificate in Food Science from Illinois Institute of Technology – 1974
   - 40 years of work experience with 30 years related to foods/drugs

2. I am one of the named inventors of the above-identified patent application and am therefore familiar with the inventions disclosed therein.

3. I have reviewed the outstanding Office Action dated January 11, 2006 pending against the above-identified patent application. As one having ordinary skill in the art, I believe that the scope of the presently pending independent Claims 1, 7 and 19 is clearly understood by the skilled artisan in view of the specification and the examples.

4. The claimed invention of the above-identified patent application relates to a method for delivering a medicament to an individual. The method comprises, in part, providing a chewing gum having at least one medicament. The medicament has a uniform distribution

throughout the chewing gum that is less than a typical amount of medicament that is swallowed by the individual to achieve a bioequivalent effect. The gum is chewed to cause the medicament to be released from the chewing gum composition into the buccal cavity of the individual. The continued chewing of the gum thereby creates a fluid pressure causing the medicament to enter the systemic system of the individual through an oral mucosa of the individual.

5. Applicants have surprisingly found that less medicament or agent can be placed in the chewing gum than is typically orally administered and swallowed by an individual to achieve the same bioequivalent effect due to the absorption of the medicament through the oral mucosa. In fact, Applicants have surprisingly found that in certain instances, for at least certain drugs and agents, the administration of the medicament or agent using chewing gum through the buccal cavity can provide an increased effect even as compared to parenteral administration.

6. The specification provides explicit guidance for assisting one having ordinary skill in the art to determine the scope the present claims. For example, the specification teaches the enhanced absorption of medicaments through the oral mucosa by using chewing gum. Oral administration of drugs is by far the most common method. When administered orally, the drugs are typically ingested or swallowed, and drug absorption usually occurs due to the transport of cells across the membranes of the epithelial cells within the gastrointestinal tract. A further issue effecting the absorption of orally administered drugs is the form of the drug.

7. One having ordinary skill in the art would understand that most orally administered drugs or medicaments are given in the form of tablets or capsules. The tablets or capsules contain a pre-determined concentration of medicament depending on the specific objectives of the medicament and the recipient of the medicament. The pre-determined amount is generally an approved FDA amount of a medicament or a standard amount commonly used in the relevant pharmaceutical or food industry. The standard amount of medicaments in capsules or tablets can also be identified by one having skill by reading the ingredient listing on a package insert or by testing using various analytical techniques such as chromatography. As a result, the

amount of medicament typically administered to achieve a desired effect or to treat a particular disorder is known or is readily ascertainable by those skilled in the art.

8. The experiments set forth in the specification provide further guidance for achieving a bioequivalent effect using a lesser amount of a medicament in a chewing gum versus the typical or standard amount of the same medicament in a tablet. For example, the caffeine study of Experiment 2 demonstrates that the administration of the medicament or agent via a chewing gum through the buccal cavity can provide an increased effect than when the same medicament or agent is swallowed in tablet form. The study compares the bioequivalent effect/bioavailability of caffeine in consumers' bloodstream after chewing caffeine containing gum versus swallowing caffeine pills. These examples demonstrate that less caffeine can be provided in the claimed product than that that is typically ingested, for example, through No Doze, and still achieve as good if not greater effect on a consumer. Experiment 4 demonstrates that the chewing gum agents are indeed adsorbed in the oral cavity.

9. For all the foregoing reasons, as one having ordinary skill in the art, I believe that Applicants' specification and the experimental examples allow the skilled artisan to determine the metes and bounds of the presently pending claims.

I further declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001, Title 18, United States Code, and that willful false statements may jeopardize the validity of this patent and any patent issuing therefrom.

Date: 3/2/06

Name: Ronald Ream